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| 51294 | 7590 | 02/28/2007 | EXAMINER | |
| HOLLINGSWORTH & FUNK, LLC | | | GILBERT, ANDREW M | |
| 8009 34TH AVE S. | | | | |
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| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|---|-----------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/774,051 Examiner Andrew M. Gilbert | WILSON, BRUCE Art Unit 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 December 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7, 9, 10 and 18-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 18-20 is/are allowed.
 6) Claim(s) 1-7 is/are rejected.
 7) Claim(s) 9 and 10 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 06 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 12/08/2006.
2. In the reply, the Applicant amended claims 1, 7, and 18.
3. Additionally, the Applicant amended the title to obviate the objection to the specification.
4. The Applicant additionally explicitly stated in the that the Applicant intends to invoke 35 USC 112(6th) paragraph for claims 18-20.

Claim Notes

5. In reference to claims 18-20, the Examiner notes that the Applicant has invoked 35 U.S.C. 112 6th paragraph by using "means for" language, reciting function, and not reciting sufficient structure of the means referred to in the specification. The Applicant explicitly stated that the Applicant intends to invoke 35 USC 112(6th) paragraph for claims 18-20 in the reply filed on 6/30/2006.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchbinder et al U.S. Pat. No. 4,757,827. Buchbinder discloses a guiding catheter system comprising: a flexible shaft having a distal end shaped (3, 23, 42 and 64); and a

handle assembly (60 and/or 62) movably coupled to the flexible shaft, the handle assembly comprising a guide member (65, Fig 6) attached to the shaft and a housing (62) movable coupled to the guide member via a multiple slot and pin arrangement (66, 67), the flexible shaft selectively movable between a plurality of discrete indexing positions of a first degree-of-freedom defined relative to the flexible shaft (col. 4), the flexible shaft restrained in the first degree-of-freedom at each indexing position of the plurality of discrete indexing positions by the multiple-slot and pin arrangement (fig. 1), the flexible shaft movable through a predetermined displacement of a second degree-of-freedom defined relative to the flexible shaft at each indexing position of the plurality of discrete indexing positions (col. 4); and wherein motion of the flexible shaft relative to the handle assembly results in a controllable sweeping motion at the distal end the flexible shaft (col. 4); as to claims 2-3, (fig. 6); as to claim 4, (66); as to claim 5, (fig. 6); as to claim 6, (66); as to claims 7 (fig. 6).

8. The Examiner further notes that, Buchbinder clearly teaches a handle movably coupled to a flexible shaft, wherein the flexible shaft is selectively movable between a plurality of discrete indexing positions of a first degree-of-freedom defined relative to the flexible shaft (figs. 1-3 and 6). Buchbinder additionally teaches a flexible shaft restrained in the first degree-of-freedom at each indexing position of the plurality of discrete indexing positions (col. 4). Note: Applicant has not indicated in the claims how the flexible shaft is being restrained in the first degree of freedom. The shaft could be restrained *manually* or by a mechanical structure. Furthermore, Buchbinder teaches a flexible shaft that is movable though a predetermined displacement of a second degree-

of-freedom defined relative to the flexible shaft at each indexing position of the plurality of discrete positions (figs. 1-3, 6 and col. 4). Finally, Buchbinder apparatus is fully capable of the various degrees of freedom because movements causes the distal end of the guidewire to deflect either toward or away from its longitudinal axis thus causing a longitudinal displacement. For the record, the device of Buchbinder is fully capable of an infinite amount of degree of freedom and is fully capable of being selectively movable between a plurality of discrete indexing positions manually. The Examiner suggests that the Applicant add additional structure and claim language to distinguish the manner that the Applicant's invention is selectively moveable and restrained to distinguish over Buchbinder. Additionally, see discussion below in "Response to Arguments".

9. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Khairkhahan et al (6179809). Khairkhahan et al discloses a guiding catheter system comprising: a flexible shaft having a distal end shaped (Figs 6a-f; Fig 9); and a handle assembly (172) movably coupled to the flexible shaft (110), the handle assembly comprising a guide member (150) attached to the shaft and a housing (156) movable coupled to the guide member via a multiple slot and pin arrangement (Fig 6D; 27, 25, 152; Figs 6a-f; col 7, Ins 30-col10, In 14), the flexible shaft selectively movable between a plurality of discrete indexing positions of a first degree-of-freedom defined relative to the flexible shaft (Figs 6a-f; col 7, Ins 30-col10, In 14), the flexible shaft restrained in the first degree-of-freedom at each indexing positions of the plurality of discrete indexing positions (Figs 6a-f; col 7, Ins 30-col10, In 14), the flexible shaft movable through a predetermined displacement of a second degree-of-freedom defined relative to the

flexible shaft at each position of the plurality of discrete indexing positions by the multiple-slot and pin arrangement (Figs 6a-f; col 7, Ins 30-col10, In 14; especially col 10, Ins 7-14); and wherein motion of the flexible shaft relative to the handle assembly results in a controllable sweeping motion at the distal end the flexible shaft (Figs 6a-f; col 7, Ins 30-col10, In 14); as to claims 2-3, (Figs 6a-f; col 7, Ins 30-col10, In 14); as to claims 4-6 (Figs 6a-f; col 7, Ins 30-col10, In 14; especially 214 and/or 216); as to claim 7 (Figs 6a-f; col 7, Ins 30-col10, In 14).

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al. West et al discloses a guiding catheter system comprising: a flexible shaft having a distal end shaped (Fig 4); and a handle assembly (38, Fig 4) movably coupled to the flexible shaft (Fig 5a; 84, and 66, 72 wherein the pull wires are movably coupled to the flexible shaft), the handle assembly comprising a guide member (42, 44) attached to the shaft and a housing (38) movable coupled to the guide member via a multiple slot and pin arrangement (Fig 4, 5a; col 10, Ins 10-20, 44-54; col 12, Ins 36-47), the flexible shaft selectively movable between a plurality of discrete indexing positions of a first degree-of-freedom defined relative to the flexible shaft (col 7, Ins 35-63; col 12, Ins 48-col 13, Ins 5), the flexible shaft restrained in the first degree-of-freedom at each indexing positions of the plurality of discrete indexing positions (col 7, Ins 35-63; col 12, Ins 48-col 13, Ins 5), the flexible shaft movable through a predetermined displacement of a second degree-of-freedom defined relative to the flexible shaft at each position of the plurality of discrete indexing positions by the multiple-slot and pin arrangement (col 7, Ins 35-63; col 12, Ins 48-col 13, Ins 5); and wherein motion of the flexible shaft relative to the

handle assembly results in a controllable sweeping motion at the distal end the flexible shaft (col 7, Ins 35-63; col 12, Ins 48-col 13, Ins 5; wherein the Examiner notes that the applicant has not require the multiple-slot and pin arrangement to require that their be a single slot, thus the two slots and pins of West et al controlling the lateral deflection as a first degree of freedom while preventing rotation in a second degree of freedom and then preventing lateral deflection while allowing rotation in the second degree of freedom at a specific lateral deflection reads on the claims. Furthermore, the Examiner notes that West et al allows for controlled specific discrete adjustments in both the first and second degrees of freedoms); as to claims 2-3, (col 7, Ins 35-63; col 12, Ins 48-col 13, Ins 5).

11. The Examiner suggests structurally defining the multiple-slot and pin as disclosed in the specific (ie – serpentine slot with circumferential channels connected by longitudinal axial segments in a serpentine fashion) to overcome the prior art rejections.

Allowable Subject Matter

12. Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 18-20 are allowed.

14. The following is a statement of reasons for the indication of allowable subject matter:

15. The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. In reference to claims 18-20, the Examiner notes that the Applicant has invoked 35 U.S.C. 112 6th paragraph. The subject matter not found was an equivalence means an equivalence means for selectively moving the shaft between the plurality of discrete positions of a first degree-of-freedom defined relative to the shaft; means for restraining a motion of the shaft in the first degree-of-freedom at each position of the plurality of discrete positions; and means for moving the flexible shaft through a second degree-of-freedom defined relative to the flexible shaft at each position of the plurality of discrete positions in combination with other elements of the claims. The means for specified in by the Applicant in the specification of a serpentine slot and pin arrangements selectively move the shaft into a plurality of discrete indexing positions, restraining the motion of the shaft in each of the discrete indexing positions, and then moving the shaft through a second degree-of-freedom at each of the plurality of discrete indexing positions. The prior art failed to teach or suggest a slot formed in by a plurality of circumferential channels (424) joined by axial segments (426) in a serpentine configuration. The circumferential channels being spaced by a longitudinal spacing distance (502) between the circumferential channels. In each longitudinal orientation the catheter shaft can rotate axially, but cannot move longitudinally relative to the handle. The axial length of each circumferential channel (424) defines a rotational angle (506) that defines the maximum angle the catheter shaft can be rotated for each given longitudinal location, or channel. Through motion of the pin though the serpentine slot, the shaft is selectively moved between a plurality of discrete longitudinal

positions, by the axial segments connecting the longitudinal channels, defining a first degree-of-freedom relative to the shaft, then restrained in further longitudinal motion by serpentine structure of the slot at each longitudinal channel and then allowing movement of the shaft through a second degree-of-freedom by the pin traveling the axial length of the circumferential channel rotating the shaft at each of the longitudinal channels as the pin follows the serpentine path of the slot.

Response to Arguments

16. Applicant's arguments filed 12/08/2006 have been fully considered but they are not persuasive.
17. The Applicant argues against the rejections of Khairkhahan et al and Buchbinder et al by stating that all three prior art references fail to disclose a multiple-slot and pin arrangement with a plurality of discrete indexing positions as a user could freely and continuously rotate the members through all possible positions and not encounter a plurality of indexing positions (Remarks, pg 7, paragraph 2, pg 8, paragraph 1-2, and 4).
18. In response to the Applicant's arguments against the devices of Khairkhahan et al and Buchbinder et al the Examiner notes that while the user is capable of being able to freely and continuously rotate the pins through the helical grooves forming the multiple slots, the user is also capable of manually stopping the rotation at a plurality of discrete positions, ie – the user is fully capable of rotating the pin along the groove 360 degrees and stopping and doing a 360 degree rotation each and every time to stop in the same discrete position. The Applicant has not structurally defined the multiple-slot so as to require that the *structure* of the multiple-slot in engagement with the pin cause

the restraining of movement. Furthermore, in devices of Khairkhahan et al and Buchbinder et al the pin can be considered as the distal-most thread engager, ie – 67 in Buchbinder and 25 in Khairkhahan. The Examiner suggests structurally defining the multiple-slot and pin as disclosed in the specific (ie – serpentine slot with circumferential channels connected by longitudinal axial segments in a serpentine fashion) to overcome the prior art rejections.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

